

**REMARKS**

Claims 44 and 47-54 are all of the claims pending in the application prior to the amendment, and claims 44 and 47-54 are currently rejected. In response, claims 44 and 48-53 are amended, claims 47 and 54 are cancelled, and claim 55 is new. Therefore, after entry of the amendment claims 44, 48-53 and 55 are all the claims pending in the application.

Claim 44 has been amended to correct for a lack of antecedent basis for “allergenicity”.

Claim 44 has been amended to include in the preamble the word “potential” and the phrase “irritancy or inflammatory characteristics.” Support for such amendments is found in the specification, for example, at page 1, line 5, page 2, lines 28-33, and page 15, line 18.

Claim 44 has been amended to recite a “chemical” in lines 2, 4, 5, and 6. Support for “chemical” is found in the specification at page 1, line 5 and page 2, line 33.

Claim 44 has been amended to replace the term “sensitizing agent” with “IgE specific for said substance or chemical.” Support for “absence of IgE” is found, for example, at page 6, line 18, and page 11, line 19. The fact that the IgE which is absent in the assay is specific for the substance or compound being investigated is also clear from the specification. For example, at page 11, lines 19-20, the specification states that the absent IgE is specific for the experimental compound, in that case termed “antigen” (antigen being a general term for a compound capable of being bound specifically by an immunoglobulin at the variable region).

Claim 44 has been amended to recite that “at least one” mast cell and/or basophil cell mediators are detected. Such is implicit in the Examples, as on page 11, Table 2, and page 9, Figure 1.

Claims 52 and 53 are amended to depend from claim 44, and to make clear that the chromogen and antibody binding assays, respectively, are means to detect a mast cell and/or basophil cell mediator. Support for the amendment to claim 52 is found in the specification at page 4, lines 20-23, and page 7, lines 20-23. Support for the amendment to claim 53 is found, for example, at page 5, first paragraph.

Claim 55 is new. Support for new claim 55 is found in the specification at page 7, lines 3-6.

Accordingly, no new matter has been added and Applicants request that the Amendment is entered.

#### Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 54 and 47 are currently rejected as containing subject matter which was not adequately described in the specification.

Applicants have cancelled claims 54 and 47.

Claims 44 and 47-54 are currently rejected as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the Examiner contends that since Benyon et al. teaches that allergens and non-allergens alike may cause release of mediators from mast-cells, the claims are not enabled as one would be unable to determine an “allergen” based on measuring release of a mediator.

In response, Applicants assert that the claims are enabled. Benyon teaches that both allergens, through an IgE-dependent pathway, and “non-immunological stimuli,” through some other pathway, can activate release of mediators from mast cells. See Benyon, page 894, second paragraph of introduction. Indeed, the present application is consistent with this view. However, the present invention also provides data to show that compounds which activate mast cell-release in an IgE-independent fashion have the “potential” to become allergenic (activate mast cell release in an IgE-dependent fashion). See page 15, Example 2. Thus, Applicants have shown a correlation between compounds that often elicit allergenic responses, and those compounds that can activate mast cell release in the absence of IgE specific for that compound. Applicants further submit a Declaration under 37 C.F.R. § 1.132 executed by an Inventor on the present application further addressing these points, and other points, related to enablement. The Declarant’s *curriculum vitae* is also provided establishing her expertise in the field.

Nevertheless, in the interest of advancing prosecution of this case, Applicants have also amended the claims to recite a method for assaying substances and chemicals for “potential allergenicity, irritancy, or inflammatory characteristics.” As amended, the claims clearly do not suggest that every compound that elicits an IgE-independent response is, by that fact alone, allergenic. See enclosed inventor’s declaration, page 12, beginning with the third full paragraph. Accordingly, Applicants assert that the claims are enabled, and respectfully request withdrawal of the rejection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 44, 47-54 are currently rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends that the term “sensitizing agent” is unclear.

In response, Applicants have amended claim 44 to recite, in place of “sensitizing agent,” “IgE specific for said substance or chemical.” This amendment makes clear that what is not present in the assay is IgE specific for the substance or compound under investigation. As stated earlier, there is support for such an amendment. Support for “absence of IgE” is found, for example, at page 6, line 18, and page 11, line 19. The fact that the particular IgE which must be absent in the assay is specific for the substance or compound being investigated is also clear from the specifications. For example, at page 11, lines 19-20, the specification states that the absent IgE is specific for the experimental compound, in that case termed “antigen” (antigen being a general term for a compound capable of being bound specifically by an immunoglobulin at the variable region). Accordingly, Applicants assert that the claims are not indefinite, and respectfully request withdrawal of the rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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CUSTOMER NUMBER

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